DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

CENTERS FOR MEDICARE & MEDICAID SERVICES

Northeast Division of Survey & Certification

ACTION REQUIRED – PLEASE READ CAREFULLY

Via certified mail

September 26, 2018

Alexander Finkelstein, M.D.
Laboratory Director
Bridgeport Hospital Laboratory
267 Grant Street
Bridgeport, CT 06610

CLIA number: 07D0099572

RE: ALLEGATION OF COMPLIANCE NOT CREDIBLE, EVIDENCE OF CORRECTION UNACCEPTABLE

Dear Dr. Finkelstein:

You were notified by our letter dated August 28, 2018 of deficiencies found at the July 20, 2018, complaint survey of your laboratory. You were requested to submit a credible allegation of compliance (AOC) and acceptable evidence of correction for the deficiencies cited within ten days of receipt of our non-compliance notification letter.

You were advised that a credible AOC is a statement or documentation that:

1) Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2) Is realistic in terms of the possibility of corrective action being accomplished between the date of the survey and the date of the allegation; and
3) Indicates the resolution of the deficiencies.

You were also advised that acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;
2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
3) What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

We received your response on September 14, 2018. We have reviewed your submission and find that it does not constitute a credible allegation of compliance and acceptable evidence of correction for the following reasons:

1. **Condition D5032**: The laboratory has failed to correct standard level deficiencies supporting this condition level deficiency.
   a) Standards D5203, D5209, D5311, D5313, D5393, D5403, D5407, D5411 and D5821:
   Documented evidence of a patient impact study not submitted.
   b) Standards D5203 Findings A and B, D5403 and D5411 :
      i. The Operator's manual states loading should be front to back and left to right and does not state to turn the slide rack 180° before loading. This deviates from the manufacturer's instructions.
   c) Standards D5203 Findings A and B and D5411:
      i. Documented evidence supporting the validation of the off label method not submitted.
   d) Standards D5203 Finding B, D5311, D5407, and D5411 :
      i. The employee education date does not correlate with the documentation received.
   e) Standards D5203 and D5411: The X5 completion date listed does not correlate with the documentation received.
   f) Standard D5209:
      i. Documentation for the evaluation of all technical supervisors not submitted.
      ii. A written delegation of duties documentation for each personnel not submitted.
      iii. Attachment F – 'Technical Competency,' you indicated the policy was updated to establish frequencies, but the policy does not include the frequencies.

iv. Competency data submitted is incomplete.

g) Standard D5393:
   i. Documentation on how the corrective action(s) are being monitored to ensure the deficient practice does not recur not submitted.
   ii. The X5 completion date is missing.

h) Standards D5393 and D5821: Attachment J, page 10 states to see a separate policy, but a separate policy was not submitted.

i) Standard D5411:
   i. This could have been referred to D5203.

2. **Condition D6108**: The laboratory has failed to address the standard level deficiencies supporting this condition level deficiency. The AOC must address and provide resolution for the deficient practice. (i.e. what will be done to ensure the technical supervisor (TS) performs their duties?)

3. **Condition D6153**: The laboratory has failed to address the standard level deficiencies supporting this condition level deficiency.
   a) Standard D6157:
      i. Documented evidence of a patient impact study not submitted.
      ii. Organizational chart incomplete.
      iii. Competency assessments do not match the organizational chart.
      iv. The AOC must address and provide resolution for the deficient practice. (i.e. what will be done to ensure the general supervisor (GS) performs their duties?)
      v. Attachment L is incorrect. The regulations require 2080 hours per year.

You are reminded that if you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, the State of Connecticut Department of Public Health State Agency (SA) will recommend to the Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate.

As you were previously advised, these may include alternative sanctions (Civil Money Penalty of up to $3,000 per day of noncompliance per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your

laboratory's CLIA certificate and cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

We are providing you another opportunity to submit a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies. You must respond WITHIN 10 DAYS from receipt of this notice.

Copies of this letter are being forwarded to the SA and to the College of American Pathologists (CAP).

If you have any questions, please contact Bethzaida Rodriguez at (617) 565-2146 or Dina Caloggero at (617) 565-1286 of my staff.

Sincerely,

Daniel M. Kristola
Branch Manager
Certification and Enforcement Branch

Enclosure: CMS-2567

Cc: Barbara Cass, Connecticut SA
Cheryl Wiseman, CMS Central Office
Amy Daniels, CAP

Cc: Dr. Finkelstein via certified, return receipt # **9171082133393968218482**